IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

THE RESEARCH FOUNDATION OF STATE UNIVERSITY OF NEW YORK; NEW YORK UNIVERSITY; GALDERMA LABORATORIES INC.; AND GALDERMA LABORATORIES, L.P., Plaintiffs, v. MYLAN PHARMACEUTICALS INC. Defendant.	C.A. No. 09-184 (JJF) (LPS) **REDACTED – PUBLIC VERSION**

PLAINTIFFS' OPENING BRIEF IN SUPPORT OF THEIR MOTION FOR PRELIMINARY INJUNCTION AND TEMPORARY RESTRAINING ORDER

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TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Cases

Statutes

Other Authorities

NATURE AND STAGE OF THE PROCEEDINGS

On March 19, 2009, Plaintiffs The Research Foundation Of State University Of New York; New York University; Galderma Laboratories Inc. and Galderma Laboratories, L.P. (collectively, "Galderma"), filed this action against Defendant Mylan Pharmaceuticals Inc. ("Mylan"). Plaintiffs' Complaint alleges, *inter alia*, that Mylan's submission of Abbreviated New Drug Application ("ANDA") No. 90-855, which seeks approval to market a generic version of Galderma's drug Oracea® ("Mylan's Generic Product") infringes U.S. Patents Nos. 7,211,267 ("the '267 Patent") (Ex. A); 7,232,572 ("the '572 Patent") (Ex. B); 5,789,395 ("the '395 Patent"), and 5,919,775 ("the '775 Patent"). *See* D.I. 1. Trial is set for December 7, 2010. *See* D.I. 26.

Plaintiffs believe that FDA approval and launch of Mylan's generic version of Oracea® may be imminent. This is Galderma's opening brief in support of its motion for a preliminary injunction and temporary restraining order.

SUMMARY OF THE ARGUMENT

A preliminary injunction is appropriate because (1) Galderma has valid and enforceable patents that are infringed by Mylan and is likely to succeed on the merits of this patent infringement suit; (2) Galderma will suffer irreparable harm if Mylan is permitted to launch its Generic Product that cannot be adequately compensated by money damages, including but not limited to irretrievable loss of market share and price erosion; (3) the balance of hardships favor Plaintiffs because Galderma stands to suffer irreversible harm should Mylan launch its Generic Products whereas Mylan will suffer little, if any harm if an injunction is granted; and (4) the public interest weighs in favor of protecting valid innovation through the patent system.

Accordingly, Plaintiffs respectfully request that the Court grant a temporary restraining order and preliminary injunction precluding Mylan from launching its Generic Product until resolution of this action.

STATEMENT OF FACTS

Oracea®, the drug at issue in this action, has helped doctors and patients treat and overcome the symptoms of rosacea. Rosacea, also known as acne rosacea, is a chronic

inflammatory skin disorder that affects approximately 14 million Americans. *See* Webster Decl. ¶ 3.[1] Signs and symptoms of rosacea may include the following: (1) flushing and redness, known as "erythema," (2) bumps and pimple-like blemishes, known as "papules and pustules," and (3) visible blood vessels, known as "telangiectasia." *See* Webster Decl. ¶ 12.

Prior to the development of Oracea®, rosacea had been treated with topical creams and gels. Physicians also commonly prescribed oral antibiotics, such as the tetracyclines doxycycline and minocycline, off-label to treat the disease. *See* Ex. E, Joseph B. Bikowski & Mitchel Goldman, 3 J. Drugs Dermatol. 251, 252 (2004) ("Bikowski 2004"); Webster Decl. ¶¶ 13-14. Prior therapy of rosacea, however, was fraught with problems.

Antibiotics, such as doxycycline, are generally prescribed to treat infections. *See* Webster Decl. ¶ 15. Infections are usually of short duration, and the normal course of antibiotics consists of use for about eight to ten days. Rosacea, however, is not an infection but a chronic inflammatory disorder. *Id*. Thus, short-term treatment is generally ineffective to treat rosacea; long-term treatment is usually required. *See id*.; Ex. F, Joseph B. Bikowski, 2 SKINmed 234 (2003) ("Bikowski 2003"), (noting that 25% of rosacea patients relapse 1 month after discontinuing active therapy consisting of systemic tetracycline); Ex. E at 252. Unfortunately, antibiotics have significant side effects that make long-term treatment undesirable. For example, antibiotics may cause dizziness, phototoxicity (increased sensitivity to light), hyperpigmentation, and gastrointestinal disturbances. More importantly, long-term use of antibiotics leads to the development of antibiotic-resistant organisms. *See* Ex. A at Col. 3:32-38; Ex. F (noting that due, in part, to the widespread use of oral antibiotics for long-term treatment of acne, resistance of the bacterium *P. acnes* to antibiotics surged from 20% in 1978 to 62% in 1996). Such antibiotic resistance has adverse effects because known antibiotics may become ineffective to treat common infections. *See* Webster Decl. ¶¶ 16-17. Additionally, long-term use of antibiotics has

[1] As used herein, "Webster Decl." refers to the Declaration of Guy F. Webster and accompanying exhibits, submitted herewith.

been shown to lead to increased risk of infection for individual patients. *See id.* at ¶ 17; Ex. G, David J. Margolis et al., 141 Arch. Dermatol. 1132, 1135 (2005) ("Margolis 2005") (concluding that the odds of a developing an upper respiratory tract infection doubled for patients who used an antibiotic to treat acne).

Prior to Oracea®, dermatologists had limited options for oral rosacea therapy. They could treat the symptoms of rosacea for short periods of time with antibiotics and limit the effectiveness of the treatments, or use antibiotics for long periods of time and risk unwanted side effects. *See* Webster Decl. ¶¶ 15-18. Thus, there was a long-standing need for an effective, long-term oral treatment of rosacea. *See id.* at ¶ 18; *see also* Ex. E at 252.

CollaGenex scientist Robert Ashley, inventor the '267 and '572 Patents, solved this long-standing problem. Mr. Ashley discovered that antibiotic doses of tetracyclines were not required to treat acne and rosacea. Instead, tetracycline compounds could be administered in ***sub-antibiotic amounts*** to effectively and safely treat the diseases without unwanted side effects. *See* Exs. A & B at Example 38. Mr. Ashley's discovery went against more than twenty-five years of teaching in the art that antibiotic doses were required to treat acne and rosacea. *See* Webster Decl. ¶¶ 86-90. Based on Mr. Ashley's discovery, CollaGenex developed Oracea® brand 40 mg doxycycline once-daily capsules. Oracea® is the commercial embodiment of the '267 and '572 Patents. *See* Ex. D (Oracea® Package Insert); Ex. H at 28; Webster Decl. ¶ 83.

On May 26, 2006, Oracea® became the first – and is still the only – oral therapy approved by the FDA for the treatment of rosacea, and is indicated for the treatment of the papules and pustules of rosacea. Oracea®, unlike traditional antibiotics, has no antimicrobial effect. *See* Webster Decl. ¶ 19. Rather, the low dose of doxycycline administered by Oracea® is ineffective to treat infection, but instead acts as an anti-inflammatory drug. *See* Webster Decl. ¶ 19. Oracea®, therefore, does not lead to antibiotic resistance, nor does it have the other undesirable side effects of traditional dose antibiotics. *See* Webster Decl. ¶ 19. As a result, Oracea® represents a significant advance over previous therapies.

Since its launch, Oracea® has been praised as "a giant step forward" in the treatment of rosacea and enjoyed considerable commercial success. *See* Ex. I. Oracea® is the leading pharmaceutical FDA-approved product and the leading branded oral pharmaceutical product prescribed for the treatment of rosacea. REDACTED [redacted]. *See* Johnson Decl. ¶ 15.[2] Oracea® is a significant asset to those suffering from rosacea, as well as to Plaintiffs.

ARGUMENT

This Court has authority to issue a preliminary injunction to protect the rights secured by a valid patent. *See* 35 U.S.C. § 283 (2006); *see also Ranbaxy Pharms., Inc. v. Apotex, Inc.*, 350 F.3d 1235, 1239 (Fed. Cir. 2003). Mylan's filing ANDA No. 90-855 constitutes infringement under 35 U.S.C. § 271(e)(2)(A) of patents that cover use of Oracea® in accordance with its FDA-approved indication. *See Yamanouchi Pharm. Co. v. Danbury Pharmacola, Inc.*, 231 F.3d 1339, 1346 (Fed. Cir. 2000). Injunctive relief is explicitly provided by statute as a remedy for this infringement. *See* 35 U.S.C. § 271(e)(4)(B).

Where a generic drug manufacturer like Mylan has filed an ANDA seeking to market generic drugs before the expiration of patents that cover a branded drug like Oracea®, it is appropriate for a district court to enjoin the likely future patent infringement pending a trial on the merits. *See, e.g., Glaxo Group Ltd. v. Apotex, Inc.*, 64 F. App'x 751, 753 (Fed. Cir. 2003); *see also Glaxo Group Ltd. v. Apotex, Inc.*, 130 F. Supp. 2d 1006, 1008 (N.D. Ill. 2001). An injunction is proper regardless of whether the future infringement would be "direct" infringement under 35 U.S.C. § 271(a) or "indirect" infringement under 35 U.S.C. § 271(b) or (c). *See, e.g., Takeda Chem. Indus., Ltd. v. Watson Pharms., Inc.*, 329 F. Supp. 2d 394, 400-403 (S.D.N.Y. 2004).

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[2] As used herein, "Johnson Decl." refers to the Declaration of Brian Johnson and accompanying exhibits, submitted herewith.

In deciding whether to grant a preliminary injunction, the court must balance four factors: (1) the patentee's likelihood of success on the merits; (2) the irreparable harm the patentee will suffer if the injunction is not granted; (3) the balance of the hardships between the parties; and (4) the public interest. *See Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1374 (Fed. Cir. 2006) (citation omitted); *see also Hybritech Inc. v. Abbott Labs.*, 849 F.2d 1446, 1451 (Fed. Cir. 1988).[3] The movant bears the burden of proof on a preliminary injunction motion, viewed in light of the proofs required at trial. *See Tate Access Floors, Inc. v. Interface Architectural Res., Inc.*, 279 F.3d 1357, 1365 (Fed. Cir. 2002). These same standards apply to the Court's decision on whether to issue a temporary restraining order. *See Tootsie Roll Indus., Inc. v. Sathers, Inc.*, 666 F. Supp. 655, 658 (D. Del. 1987).

I. GALDERMA IS LIKELY TO SUCCEED ON THE MERITS

To establish likelihood of success on the merits, Galderma must show that, in light of the presumptions and burdens that will inhere at a trial on the merits, (1) it will likely prove infringement and (2) its infringement claims will likely withstand Mylan's challenges to the validity of the patents. *See Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1364 (Fed. Cir. 1997). Galderma is likely to succeed in establishing that Mylan has infringed and will infringe the claims of at least the '267 and '572 Patents ("the Ashley Patents"),[4] and is also likely to succeed on the merits in rebutting any challenge by Mylan to the validity of those patents.[5]

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[3] This Court follows Federal Circuit precedent in deciding whether to issue a preliminary injunction enjoining the marketing and sale of a patented drug. *See Lab. Corp. of Am. Holdings v. Chiron Corp.*, 384 F.3d 1326, 1330-31 (Fed. Cir. 2004).

[4] For purposes of this motion, only the '267 and '572 Patents will be discussed.

[5] At 11:38 p.m. on April 1, 2010 – the night before this motion was due – Mylan notified Plaintiffs that Mylan will seek leave to assert inequitable conduct. Mylan's untimely claims, first raised over four months after the deadline to amend the pleadings (*see* D.I. 26), are not properly before the Court at this time. Mylan, therefore, should not be permitted to raise them in response to Plaintiffs' motion. To the extent that the Court permits Mylan to amend its pleadings or otherwise argue unenforceability, Plaintiffs reserve the right to address the issue in their reply brief or other appropriate pleading.

A. Mylan Infringes, And Will Induce And Contribute To Infringement

By submitting its ANDA seeking approval to market a generic version of Galderma's Oracea® product, Mylan has infringed the patents-in-suit under 35 U.S.C. § 271(e)(2). Further, by marketing and selling its proposed generic version of Oracea®, Mylan will induce others to infringe and contribute to infringement of the patents-in-suit under 35 U.S.C. §§ 271(b) and (c).

1. By Filing Its ANDA, Mylan Has Infringed Galderma's Patents

Mylan's files ANDA No. 90-855 with a Paragraph IV certification that it intends to market its Generic Product prior to the expiration of the Ashley patents. This action constitutes infringement of Plaintiffs' patents. *See Yamanouchi*, 231 F.3d at 1346; 35 U.S.C. § 271(e)(2) ("The mere act of filing an ANDA constitutes infringement.").

The '572 and '267 Patents claim methods of treatment. The inquiry under 35 U.S.C. § 271(e)(2), therefore, is to determine whether the use of Mylan's Generic Product as described by its ANDA falls within a claimed method of treatment. *See Abbott Labs. v. Torpharm, Inc.*, 300 F.3d 1367, 1373 (Fed. Cir. 2002) ("Because [generic] drug manufacturers are bound by strict statutory provisions to sell only those products that comport with the ANDA's description of the drug, an ANDA specification defining a proposed generic drug in a manner that directly addresses the issue of infringement will control the infringement inquiry."); *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997). The proposed generic version of the patented drug infringes if its use, as set forth in its ANDA, fulfills the elements recited in the asserted claims, either literally or under the doctrine of equivalents. *See, e.g., Abraxis Bioscience, Inc. v. Navinta, LLC*, 640 F. Supp. 2d 553, 569 (D.N.J. 2009).

a. Use Of Mylan's Generic Product Infringes The '267 Patent

REDACTED

REDACTED. As described below and in the Claim Chart attached as Exhibit C, use of Mylan's Generic Product literally infringes at least Claims 1, 22, 24, and 26 of the '267 Patent.[6]

Independent Claim 1 of the '267 Patent has five elements: (1) A method of treating acne in a human in need thereof comprising (2) administering orally or intravenously to said human an antibiotic tetracycline compound (3) in a sub-antibacterial amount that reduces lesion count, said amount being 10-80% of the antibacterial effective amount; (4) wherein the tetracycline compound is administered long term, (5) without administering a bisphosphonate compound. *See* Ex. A at Claim 1. Use of Mylan's Generic Product meets very element of Claim 1.

First Limitation: REDACTED

The parties agree that the term "acne" includes rosacea. *See* D.I. 56 at Exhibit 16; *see also* Ex. A at Col. 4:25-45. Thus, doctors and patients will use Mylan's Generic Product in a method of treating acne in a human in need thereof. *See* Webster Decl. ¶ 28.

Second Limitation: REDACTED The active ingredient of Mylan's Generic Product is the antibiotic tetracycline compound doxycycline. *See, e.g.,* REDACTED Webster Decl. ¶ 29.

Third Limitation: Claim 1 requires administering a sub-antibacterial amount that reduces lesion count, said amount being 10-80% of the antibacterial effective amount. REDACTED *See, e.g.,* REDACTED

[6] For purposes of this motion, only exemplary claims will be discussed. The attached infringement chart demonstrates Mylan's infringement of the asserted claims of the '267 and '572 Patents. *See* Ex. C.

REDACTED

See also Webster Decl. ¶ 30.

"Amount," as used in the patent, means dose or serum level. *See* D.I. 56 at Ex. 16. Mylan infringes under either definition. REDACTED *See* Ex. A at Col. 5:47-57 ("Some examples of antibiotic doses of members of the tetracycline family include 50, 75, and 100 mg/day of doxycycline…"); Webster Decl. ¶ 31.

REDACTED The patent specification and prosecution history set forth that 1.0 µg/ml is the minimum antibiotic serum concentration for doxycycline. *See* Ex. A at Col. 6:36-40. Thus, when "amount" is described in terms of serum concentration, patients taking Mylan's 40 mg Generic Product will be administered approximately 60% of the antibacterial effective amount of the antibiotic tetracycline compound. *See* Webster Decl. ¶ 32.

Fourth Limitation: Claim 1 requires that the tetracycline compound be administered long term. The parties agree that "long term" means a period of time longer than eight to ten days. *See* D.I. 56 at Exhibit 16. REDACTED

[7] Even under Mylan's proposed constructions of the claim terms "sub-antibacterial amount" and "the antibacterial effective amount," Mylan's product infringes. *See* Webster Decl. ¶ 31.

REDACTED

Thus, doctors and patients using Mylan's Generic Product will meet this element. *See id.*

Fifth Limitation: REDACTED

Thus, doctors and patients using Mylan's Generic Product meet the fifth element of Claim 1. *See* Webster Decl. ¶ 35.

Dependent Claim 22 recites: "A method according to Claim 1, wherein said acne is acne rosacea." Similarly, Claim 24 depends from Claim 1 and provides that the human has skin lesions associated with acne; and Claim 26 specifies that those lesions are papules and pustules. *See* Ex. A at Claims 22, 24, and 26. REDACTED

Therefore, use of Mylan's Generic Products REDACTED literally infringes at least Claims 1, 22, 24, and 26 of the '267 Patent.

b. Use Of Mylan's Generic Product Infringes The '572 Patent

As described below and in the appended Claim Chart attached as Exhibit C, use of Mylan's Generic Product literally infringes at least Claims 1, 12 and 14 of the '572 Patent.

Independent Claim 1 of the '572 Patent has six elements: (1) A method for treating papules and pustules of rosacea in a human in need thereof comprising (2) administering orally to said human a tetracycline compound, or a pharmaceutically acceptable salt thereof, (3) in an amount that is effective to treat the papules and pustules of rosacea, but has substantially no

antibiotic activity, said amount being 10-80% of the antibiotic amount, (4) wherein the tetracycline compound is an antibiotic tetracycline compound or a pharmaceutically acceptable salt thereof (5) administered in an amount that results in no reduction of skin microflora during a six-month treatment, (6) without administering a bisphosphonate compound. *See* Ex. B at Claim 1. Use of Mylan's Generic Product REDACTED meets each and every element of Claim 1.

First, Second and Fourth Limitations: REDACTED

Third Limitation: Mylan's Generic Product will be administered in an amount that is effective to treat the papules and pustules of rosacea, but has substantially no antibiotic activity, said amount being 10-80% of the antibiotic amount. REDACTED Moreover, as set forth above, when "amount" is defined as serum level, patients administered Mylan's Generic Product will have a serum concentration that is approximately 60% of the antibiotic amount of the antibiotic tetracycline compound doxycycline. *See* Webster Decl. ¶ 42.

Fifth Limitation: Mylan's Generic Product is administered in an amount that results in no reduction of skin microflora during a six-month treatment period. REDACTED

[8] The parties disagree over the term "the antibiotic amount" and whether "an amount that . . . has substantially no antibiotic activity" is a claim term. Even under Mylan's proposed constructions, Mylan's Generic Product infringes. *See* Note 7, *supra*; Webster Decl. ¶ 42.

REDACTED

Further, as set forth in the declaration of Dr. Webster, treatment with Oracea® and Mylan's Generic Product REDACTED results in administration of doxycycline in an amount that results no reduction of skin microflora over a six month period. *See* Webster Decl. ¶¶ 43-45. REDACTED a peer-reviewed publication, and Example 38 of the '572 Patent, each confirm that a six-month treatment with doxycycline at a daily dosage of 40 mg resulted in no reduction of skin microflora when compared with placebo. *See, e.g.*, Ex. M Robert Skidmore et al., *Effects of Subantimicrobial-Dose Doxycycline in the Treatment of Moderate Acne*, 139 Arch. Dermatol. 459, 462 (2003) ("Skidmore 2003"); REDACTED

Sixth Limitation: REDACTED

Thus, doctors and patients using Mylan's Generic Product meet the sixth element of Claim 1. *See* Webster Decl. ¶ 46.

Dependent Claim 12 provides that the tetracycline compound is doxycycline or a pharmaceutically acceptable salt thereof and dependent Claim 14 provides that the doxycycline or a pharmaceutically acceptable salt thereof is administered in an amount of 40 milligrams. REDACTED

Therefore, use of Mylan's Generic Products in accordance with its proposed package insert meets the additional limitations of Claims 12 and 14 of the '572 Patent. *See Baxter Healthcare Corp. v. Spectramed, Inc.*, 49 F.3d 1575, 1582 (Fed. Cir. 1995).

Therefore, use of Mylan's Generic Products in accordance with Mylan's Label literally infringes at least Claims 1, 12, and 14 of the '572 Patent.

2. Mylan Will Induce Infringement Of The Ashley Patents

"Statements in a package insert that encourage infringing use of a drug product are alone sufficient to establish intent to encourage direct infringement." *See, e.g.*, *Abraxis Bioscience*, 640 F. Supp. 2d at 570; *see also Minnesota Mining & Mfg. Co. v. Chemque, Inc.*, 303 F.3d 1294, 1305 (Fed. Cir. 2002).

REDACTED

Mylan, therefore, has infringed the '572 and '267 Patents under 35 U.S.C. § 271(e)(2). Moreover, if Mylan is permitted to market and sell its proposed generic version of Oracea®, it will induce infringement under 35 U.S.C. § 271(b).

3. Mylan Will Contribute To Infringement Of The Ashley Patents

Mylan will also contribute to infringement of the patents. Mylan's Generic Product is especially adapted for use in connection with the methods claimed in the '267 and '572 Patents. *See* Section I.A.1, *supra*. Thus, Mylan contributes to infringement of the claimed methods. *See* 35 U.S.C. § 271(e)(2); *Abraxis Bioscience*, 640 F. Supp. 2d at 569-71, 579-80; *Golden Blount, Inc. v. Robert H. Peterson Co.*, 438 F.3d 1354, 1363-64 (Fed. Cir. 2006) (finding contributory infringement where the defendant provided the allegedly infringing product with "instruction sheets [that] taught only the infringing configuration"). If Mylan is permitted to sell its proposed generic version of Oracea®, it will contribute to infringement under 35 U.S.C. § 271(c). *See id.*

4. Mylan Asserts No Credible Theory Of Non-Infringement

Mylan provides three theories to support its position that it will not infringe the claims of the '267 and '572 Patents. *See* Ex. N. Each is without merit.

First, Mylan alleges that it will not directly infringe the claims of the '267 and '572 Patents because Mylan will not itself administer its Generic Product to humans. But, Mylan will contribute to and induce infringement of the Ashley patents. *See* Sections I.A.2-3, *supra*.

Second, Mylan asserts that it cannot be held liable for inducement because it "will not knowingly aid and abet infringement." Ex. N. REDACTED [redacted] Mylan, therefore, is liable for inducement. *See, e.g.*, *Abraxis Bioscience*, 640 F. Supp. 2d at 570 ("[The generic manufacturer's] Labeling instructs clinicians to use the ANDA Products in a manner that would practice the method of claim 6, and therefore instructs physicians to infringe claim 6.").

Finally, Mylan asserts that substantial non-infringing uses exist for its product. [redacted] REDACTED [redacted] Mylan has not – and cannot – demonstrate that substantial non-infringing uses exist for its proposed generic product. *See Abraxis Bioscience*, 640 F. Supp. 2d at 571 (holding that the alleged infringer bears the burden of establishing substantial, non-infringing uses). Moreover, substantial non-infringing use is only a defense to contributory infringement, not to inducement. *See, e.g.*, *Dynacore Holdings Corp. v. U.S. Philips Corp.*, 363 F.3d 1263, 1276 n.6 (Fed. Cir. 2004).

B. Mylan Cannot Overcome The Presumption Of Validity

1. Mylan Bears A Heavy Burden To Overcome The Presumption

The '267 and '572 Patents are presumed valid. 35 U.S.C. § 282. The "presumption may be rebutted only by clear and convincing evidence." *Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 837

F.2d 1044, 1050 (Fed. Cir. 1988). In a request for a preliminary injunction, the "burden of establishing invalidity remains on the challenger." *H.H. Robertson, Co. v. United Steel Deck, Inc.*, 820 F.2d 384, 387 (Fed. Cir. 1987). Thus, "if [Mylan] fails to identify any persuasive evidence of invalidity, the very existence of the patent satisfies [Plaintiffs'] burden on validity." *Purdue Pharma L.P. v. Boehringer Ingelheim GmbH*, 237 F.3d 1359, 1365 (Fed. Cir. 2001). The burden of proving invalidity is particularly heavy where the art cited by the alleged infringer was considered by the Patent Office before allowing the claims. *See, e.g., Abbott Labs. v. Syntron Bioresearch, Inc.*, 334 F.3d 1343, 1357 (Fed. Cir. 2003); *McGinley v. Franklin Sports, Inc.*, 262 F.3d 1339, 1353 (Fed. Cir. 2001).

2. The Patent Office Issued The '267 Patent Over The Prior Art

During the prosecution of the '267 Patent, the relevant prior art was disclosed to the Patent Office. *See* Ex. O. The Patent Office considered these references and issued the claims of the '267 Patent over the prior art. *See* Ex. P.

Among other references, the Examiner cited several publications relating to the treatment of acne with ***antibiotic dosages of tetracyclines***, including doxycycline. As noted by the Applicant, however, none of the references disclosed, let alone suggested, Mr. Ashley's counterintuitive discovery: that the systemic administration of ***sub-antibiotic dosages of tetracyclines*** would be effective in treating acne. *See* Ex. Q at 20-21); Ex. R at 20-22. Indeed, at least one of the references, Hirohiko Akamatsu et al., 72 Acta Derm. Venereol. (Stockh) 178, 179 (1992) ("Akamatsu I"), suggested exactly the opposite: that the clinical efficacy of doxycycline in the treatment of acne is due, at least in significant part, to the antibiotic effects of the drug on the bacterium *P. acnes*. *See* Ex. R at 20; Webster Decl. ¶ 64 & Ex. 22 at 179.

The Examiner also cited U.S. Patent No. 6,673,843 ("the Arbiser Patent") in view of G. F. Webster et al., 21 Antimicrobial Agents and Chemotherapy 770, 772 (1982) ("Webster 1982") and Gerd Plewig & Albert M. Klingman, Acne: Morphogenesis and Treatment 261, 297 (Springer-Verlag, Berlin-Heidelberg 1975) ("Plewig 1975"), among other references. But none

of the cited references taught the use of sub-antibiotic dosages of tetracyclines to treat acne. *See* Ex. S; Ex. T; Webster Decl. ¶¶ 68-69 & Exs. 27-28.

According to the Examiner, the Arbiser Patent taught the use of angiogenesis inhibitors, including tetracyclines and chemically modified tetracyclines, to treat various skin disorders, including acne rosacea. *See* Ex. U at 25. However, the Arbiser Patent taught that angiogenesis inhibitors should be administered topically – not orally – to treat skin disorders. *See* Ex. (U at 25; Ex. S at 11-12; Ex. T at 10; Webster Decl. ¶ 68. More importantly, the Arbiser Patent did not teach the amount of tetracycline being administered. As explained by the Applicant, that Arbiser failed to teach the use of sub-antibacterial doses of tetracyclines to treat acne was an important omission:

> ***[T]he limitation that a tetracycline compound is administered "in a sub-antibacterial amount" is, in fact, a critical feature of the invention.*** The applicant's conception of a sub-antibacterial dose of a tetracycline is much more than merely the discovery of "the optimum or workable ranges by routine experimentation. " This limitation was not taught, generally or otherwise, in the prior art.

Ex. S (emphasis added).

Like Arbiser, neither of the secondary references cited by the Examiner taught use of sub-antibacterial doses of tetracyclines to treat acne. *See* Ex. S; Ex. T; Webster Decl. ¶¶ 64, 69. At least one of the cited references taught exactly the opposite. *See, e.g.*, Webster Decl. Ex. 17 at 298 (discussing the use of antibiotics in treating inflammatory acne and stating "[a]ll these considerations imply that ***it is the antibiotic activity of antibiotics that accounts for therapeutic benefits***.") (emphasis added); Webster Decl. ¶ 64. The Examiner affirmed the patentability of the subject matter over the cited references. Ex. P at 3.

Mylan cannot identify any persuasive evidence of invalidity of the '267 Patent. Under these circumstances, Mylan cannot meet its burden on the issue of validity. *See Purdue Pharma*, 237 F.3d at 1365.

3. The Patent Office Issued The '572 Patent Over The Prior Art

The '572 Patent is a continuation of the '267 Patent. As with the prosecution of the '267 Patent, the relevant prior art was disclosed to the Patent Office. *See* Ex. V. The Patent Office considered these prior art references and issued the claims of the '572 Patent. *See* Ex. W.

In particular, the Examiner cited as prior art U.S. Patent No. 6,455,583 ("the Pflugfelder Patent"), in view of other prior art including the Arbiser Patent, *supra*, U.S. Patent No. 5,260,292 ("the Robinson Patent"), Reynold C. Wong et al., 11 J. Am. Acad. Dermatol. 1076, 1081 (1984) ("Wong 1984"). *See* Ex. H at 12-28.

The Pflugfelder Patent, entitled "Method for Treating Meibomian Gland Disease", teaches a method for treating meibomian gland disease by orally administering tetracycline compounds and chemically modified tetracycline compounds. *See* Ex. H at 14. However, as explained by the Applicant, meibomian gland disease and rosacea are distinct clinical disorders. *See* Ex. H at 12. For example, according to the Pflugfelder Patent, "Meibomian gland disease is the most common tear film and ocular surface disorder causing eye irritation." Webster Decl. ¶ 63 & Ex. 21 at Col. 1:8-10. Symptoms include "blurred or filmy vision, burning or foreign body sensations in the eye, photophobia, and pain." Webster Decl. Ex. 21 at Col. 1:19-20. Rosacea, in contrast, is characterized by inflammatory lesions, erythema and telangiectasia. *See* Ex. H at 12; Webster Decl. ¶ 63. The Patent Examiner appreciated these distinctions and stated that the Pflugfelder Patent did not teach the methods of the invention. Ex. W at 3.

Mylan cannot identify any persuasive evidence of invalidity of the '572 Patent. Under these circumstances, Mylan cannot meet its burden on the issue of validity. *See Purdue Pharma*, 237 F.3d at 1365.

4. Mylan Cannot Meet Its Burden To Show Invalidity

In its response to Plaintiffs' interrogatories, Mylan has identified a laundry list of references that it contends renders the claims of the Ashley patents invalid. *See* Ex. N. As discussed more fully below, many of these patents and references were specifically considered by the Examiners in allowing the claims of the Ashley patents. The remainder are cumulative.

The principal reference relied on by Mylan in its Paragraph IV Notice Letter is the Pflugfelder Patent. *See* Ex. X. As discussed in Section I.B.3, the Pflugfelder Patent was considered by the Examiner during prosecution. The claims were allowed over that reference, because, among other things, the claims of the Ashley patents and the disclosure of the Pflugfelder Patent are directed to distinct clinical diseases. *See also* Webster Decl. ¶ 63. Thus, the claims of the Ashley patents are distinguishable over Pflugfelder. *See Eli Lilly & Co. v. Teva Pharms. USA, Inc.*, No. 02-0512-C-B/S, 2004 U.S. Dist. LEXIS 14724 (S.D. Ind. July 29, 2004), *aff'd*, No. 05-1044, 2005 U.S. App. LEXIS 14583 (Fed. Cir. July 13, 2005) (holding that the use of Prozac® in treating PMS was not obvious in light of the known use of Prozac® to treat depression because, among other things, although depressed mood is a symptom of PMS, PMS is a condition wholly distinct from depression and the etiology of PMS is unknown).

Like the Pflugfelder Patent, other references relied on by Mylan similarly disclose the use of tetracyclines to treat diseases other than acne or rosacea, and, therefore are readily distinguishable. *See* Webster Decl. ¶¶ 75-76.

Mylan also relies on a number of references that teach the administration of ***antibiotic amounts*** of tetracyclines to treat acne. Importantly, several of these references were specifically considered by the Examiner and/or summarized in a reference, Bikowski 2003 (Ex. F), that was provided to the Examiner during the prosecution of both Ashley patents as evidence of ***teaching away from the claimed invention***. As explained by the Applicant:

> Dr. Bikowski summarizes prior art studies that were designed to measure the efficacy of tetracyclines to treat acne in Tables I and II. ***In all cases, an antibacterial dose was used.***

Ex. H at 30; Ex. S at 26 (emphasis added). Accordingly, if anything, the references cited by Mylan support the ***novelty and validity*** of the claimed invention. *See* Webster Decl. ¶¶ 78-79.

Mylan contends that Hirohiko Akamatsu et al., 283 Arch. Dermatol. Res. 524 (1991)) ("Akamatsu II") renders the claimed invention anticipated or obvious. Akamatsu II, however, is cumulative of the Akamatsu I and Webster 1982 references specifically considered by the

Examiner during the prosecution of the '267 Patent. *See* Section I.B.2, *supra*; *see also* Webster Decl. ¶ 79. Indeed, Akamatsu II teaches that the efficacy of minocycline in treating acne, is due, in part, to the reduction of comedonal bacteria, *i.e.*, its antibacterial activities. *See* Webster Decl. ¶ 79 & Ex. 37 at 528.

Finally, Mylan relies on several review articles and other references that are cumulative of references disclosed in the prosecution history. Such references are either general disclosures of the uses of tetracyclines, references that were specifically considered by the Examiner and responded to by the Applicant, or references directed to sustained or controlled release formulations generally. *See* Webster Decl. ¶ 80.

Mylan also asserts that the claims of the Ashley patents are indefinite pursuant to 35 U.S.C. § 112 because there is "substantial inconsistency in the numerical values provided in the Ashley patents." Ex. N. For support, Mylan alleges that the patent specification teaches that 38 mg of minocycline taken four times a day is a "non-antibitoitic dose" but that 50 mg taken once a day is an "antibiotic dose." *Id.* Mylan argues that the claims are indefinite because a higher daily dose is considered "non-antibiotic" and would fall within the scope of the claims, whereas a lower daily dose is "antibiotic" and would not be covered by the patent. *Id.* Mylan's argument is without merit. As one of skill in the art would readily appreciate, it is not the total daily dose, but rather the lack of antibiotic effect of a particular administered amount that is the key to the invention. *See* Webster Decl. ¶ 94. Accordingly, one of skill would recognize that at 38 mg, a dose of minocycline (even if taken several times a day) would not significantly effect the growth of microbes (i.e. is a sub-antimicrobial amount), but that a single daily dose of 50 mg would act as an antibiotic. *Id.* Thus, one of skill is able to determine the scope of the claimed invention.[9] *See Exxon Research & Eng'g Co. v. United States*, 265 F.3d 1371, 1375 (Fed. Cir. 2001).

[9] Notably, Mylan's only example of indefiniteness is based on a different tetracycline compound than the one at issue here, and several dependent claims of the patents are directed to specific doses of doxycycline that could not be indefinite under Mylan's argument. *See, e.g.*, Ex. A at Claim 21; Ex. B at Claim 14.

Accordingly, Mylan is unable to identify any persuasive evidence of invalidity of the Ashley patents. *See, e.g., Syntron*, 334 F.3d at 1357; *Northern Telecom, Inc. v. Datapoint Corp.*, 908 F.2d 931, 939 (Fed. Cir. 1990). Plaintiffs, therefore, are likely to succeed on the merits regarding the issue of validity. *See Purdue Pharma*, 237 F.3d at 1365.

5. Objective Indicia Demonstrate Non-obviousness Of The Patents

A number of objective indicia of non-obviousness, including long-felt need, failure of others, unexpected results, praise by industry, commercial success, and copying demonstrate the validity of the Ashley Patents. Such objective indicia are often the most probative evidence. *Gambro Lundia AB v. Baxter Healthcare Corp.*, 110 F.3d 1573, 1579 (Fed. Cir. 1997).

a. Oracea® Satisfied A Long-Felt Need

Prior to the invention of Oracea®, the most common treatment for rosacea was antibiotic doses of tetracycline compounds, including doxycycline. *See* Webster Decl. ¶ 86. Such treatments, however, had significant disadvantages. In particular, long-term use of antibiotic doses of tetracyclines can lead to the development of antibiotic-resistant organisms and causes other unwanted side effects such as dizziness, phototoxicity (increased sensitivity to light), allergic reaction, and hyperpigmentation. *See* Ex. A at Col. 3:32-38; *See* Webster Decl. ¶¶ 15-17. These long-term effects create a "serious problem" given that rosacea is a chronic disease that requires long-term therapy or repeated treatment of recurrences. *See* Ex. E at 252.

Therefore, a long-felt, unmet need existed for effective oral treatments of acne and rosacea that would not cause antibiotic resistance and other unwanted effects. *See* Webster Decl. ¶¶ 18, 84; Ex. E at 252 (chronicling the problems associated with antibiotic treatments of rosacea and noting that "[t]here have not been any major advances in systemic treatments for rosacea for several decades.").

The launch of Plaintiffs' drug Oracea®, the commercial embodiment of the Ashley

patents, fulfilled this need.[10] *See* Webster Decl. ¶ 85. As shown by clinical studies, Oracea®, which contains 40 mg doxycycline, is as effective as 100 mg doxycycline in treating the symptoms of rosacea but has significantly fewer side effects. *See id.* at ¶¶ 20, 85 & Exs. 11, 12. *See also* Ex. D. Accordingly, long-felt need supports the patentability of the claimed invention. See *Eli Lilly & Co. v. Zenith Goldline Pharms., Inc.*, 471 F.3d 1369, 1380 (Fed. Cir. 2006).

b. Failure Of Others And Unexpected Results Demonstrate The Validity Of The Ashley Patents

To those skilled in the art, Mr. Ashley's discovery was surprising and counterintuitive. As set forth Dr. Webster's declaration, those of skill in the art initially were skeptical of Mr. Ashley's invention and the efficacy of Oracea® because it went against more than twenty-five years of teaching in the art that antibiotic doses were required to treat acne and acne rosacea. *See* Webster Decl. ¶¶ 86-89. Indeed, at the same time Oracea® was launched, Plaintiffs' competitor, Medicis Pharmaceutical Corporation, launched Solodyn®, a new full-dose ***antibiotic*** tetracycline treatment for acne. *See* Webster Decl. ¶ 90.

The contemporaneous launch of a new antibiotic for dermatologic use demonstrates the novelty and non-obviousness of the inventions claimed in the patents covering Oracea®. Had the prior art shown that acne could be treated with a sub-antibacterial dose of tetracycline, one would have expected the developers of new acne products such as Solodyn® to have attempted to avoid the known disadvantages of administering an antibacterial dose. Thus, failure of others and unexpected results provide strong support for the validity of the claimed invention. *See Zenith*, 471 F.3d at 1380; *Gambro*, 110 F.3d at 1579.

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[10] The administration of Oracea® according to the package insert is covered by the claims of the '267 and '572 Patents. *See, e.g.*, Ex. D; Ex. H at 28; Exs. A, B at Example 38; Webster Decl. ¶ 83.

c. Praise Of Oracea® In The Dermatologic Community

The industry press at the time of Oracea®'s launch confirms that it was a new and different drug with unexpected benefits. For example, in August 2006, Dermatology Times, a respected dermatological journal, published in interview with Dr. James Del Rosso, Clinical Associate Professor in the Department of Dermatology, University of Nevada School of Medicine.[11] In that interview, Dr. Del Rosso stated that the treatment of rosacea "has taken ***a giant step forward*** with the Food and Drug Administration's recent approval of Oracea." *See* Ex. I (emphasis added). Dr. Del Rosso explained:

> Oracea's availability provides a convenient, effective and safe oral therapy option that works through anti-inflammatory activity and does not produce any antibiotic effects. ***Oracea is the only oral formulation available that can make that claim***. . . .

Id. (emphasis added).

Other periodicals similarly praised the uniqueness and attributes of Oracea®. For example, the November 2007 edition of Women's Health lauded Oracea® as "[t]he best new breakthrough for your skin" and "the first pill you can safely use long-term to treat your condition [*i.e.* rosacea]." *See* Ex. J. *See also* Webster Decl. ¶¶ 19-20.

d. Oracea® Is Commercially Successful

The therapeutic benefits of Oracea® reported by the industry and popular press have borne out in clinical practice. REDACTED [redacted]. Thus, the commercial success of Oracea® supports the validity of the claimed invention. *See Alcon, Inc. v. Teva Pharms. USA, Inc.*, Civ. No. 06-234-SLR, 2009 U.S. Dist. LEXIS 97757, at *54 (D. Del. Oct. 19, 2009). *See also* Webster Decl. ¶ 91.

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[11] As Mylan noted in its responsive claim construction brief, Dr. Del Rosso is a consultant for CollaGenex and/or Galderma. Mylan, however, does not dispute that Dr. Del Rosso is a leading expert in the field.

e. At Least Three Generic Companies Have Sought To Copy Oracea® Despite The Existence Of Generic Doxycycline

To date, three different generic manufacturers, Mylan, Impax, and Lupin have filed an ANDA to market generic versions of Oracea®. *See* C.A. No. 09-483 (D. Del.), C.A. No. 09-703 (D. Del.). Copying by others is particularly telling, where, as here, the prior art is available in generic form. *See Forest Labs., Inc. v. Ivax Pharms., Inc.*, 438 F. Supp. 2d 479, 496 (D. Del. 2006) (Farnan, J.) ("In the Court's view, the copying of others is particularly telling in this case, because citalopram [the prior art drug] is currently available as a generic drug. Indeed, citalopram is sold generically by Defendants, yet Defendants seek to copy and sell Lexapro®."). Indeed, Mylan has marketed 50 mg tablets of doxycycline for the treatment of a range of infections and as "useful adjunctive therapy" in "severe acne" since at least November 6, 2006. *See*, e.g., Ex. Y. Accordingly, copying by others, including Mylan, supports the patentability of the Ashley patents. *See Forest Labs*., 438 F. Supp. 2d at 496.

II. GALDERMA WILL SUFFER IRREPARABLE HARM IF MYLAN IS NOT ENJOINED

Plaintiffs are likely to succeed in proving that Mylan infringes valid claims of the '572 and the '267 Patents, and therefore, there is a presumption that they will suffer irreparable harm if Mylan is not enjoined from making and selling its Generic Product. *See Reebok Int'l Ltd. v. J. Baker, Inc.*, 32 F.3d 1552 (Fed. Cir. 1994); *Purdue Pharma*, 237 F.3d at 1363; *Roper Corp. v. Litton Sys., Inc.*, 757 F.2d 1266, 1271-72 (Fed. Cir. 1985). The presumption of irreparable harm protects patentees "against future infringement . . . which may have market effects never fully compensable in money." *Atlas Powder Co. v. Ireco Chems.*, 773 F.2d 1230, 1233 (Fed. Cir. 1985). In any event, Plaintiffs can demonstrate that they would be irreparably harmed in ways not compensable by monetary damages if Mylan is not enjoined.

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As set forth in the declaration of expert economist Jerry Hausman, Ph.D, it is well-recognized in the pharmaceutical industry that generic competition typically eviscerates the market share of a patented drug. It is common for a branded drug to lose over 90% of market share to generics, with as much as 70% market share lost in the first six months of generic competition. *See* Hausman Decl. ¶ 9.[12] REDACTED

[12] As used herein, "Hausman Decl." refers to the Declaration of Jerry Hausman and accompanying exhibits, submitted herewith.

REDACTED

REDACTED

III. THE BALANCE OF HARDSHIPS CLEARLY FAVORS GALDERMA

A. Without A Preliminary Injunction, Galderma Will Face Large Losses

The severe and irreversible harm that Galderma will suffer if Mylan is not enjoined from marketing and selling the Generic Products until a final decision on the merits far outweighs the minimal harm to Mylan – if any – that may result if a preliminary injunction is granted. Galderma's patent exclusivity serves the dual function of allowing Galderma to recoup the investment costs in creating an improved rosacea therapy for the public benefit and rewarding Galderma's risk in making this substantial investment. *See Eli Lilly & Co. v. Premo Pharm. Labs., Inc.*, 630 F.2d 120, 137-38 (3d Cir. 1980).

Galderma and its predecessor CollaGenex invested substantial resources of time, money and talent to bring Oracea® to the market. Before Oracea®, the FDA had never approved any sub-antibiotic dose of doxycycline (or any other oral therapy) for the treatment of rosacea. Thus, CollaGenex designed and conducted several large, multicenter clinical trials investigating the safety and efficacy of Oracea®. REDACTED

Additionally, Galderma and its predecessor CollaGenex spent significant effort and time in building a market for Oracea®. REDACTED Moreover, Galderma has spent significant time and effort running educational programming to inform individuals affected with rosacea about the disease as well as treatment options.

REDACTED . In light of such losses, and consequently Galderma's inability to benefit from its substantial expenditures and efforts for the research, development and marketing of Oracea®, the

launch of Mylan's Generic Products would cause tremendous harm to Galderma that could not be readily compensated by monetary damages. *See Purdue Pharma*, 237 F.3d at 1368.

B. An Injunction Would Cause Minimal Or No Hardship To Mylan

In contrast, Mylan has only made a minimal investment in its Generic Products. Mylan's hardship, if the injunction were granted and Mylan ultimately prevailed at trial, would be "reasonably quantifiable and capable of being protected against by a bond if need be." *Sandoz*, 500 F. Supp. 2d at 844. *See also Sanofi-Synthelabo*, 470 F.3d at 1383 (rejecting hardship claim of generic challenger whose "harms were 'almost entirely preventable' and were the result of its own calculated risk to launch its product pre-judgment").

The cost for a generic company to bring a drug to market is much lower than for an innovative drug company to introduce a new drug like Oracea®. Galderma and its predecessor CollaGenex expended significant resources on researching and developing Oracea®. In contrast, Mylan seeks approval for its Generic Products on the basis of the safety and efficacy data submitted by CollaGenex for Oracea®, *i.e.*, on the shoulders of the extensive effort and expense undertaken by CollaGenex to establish the safety and efficacy of Oracea®. REDACTED

As a generic company copying an innovative drug, Mylan does not need to develop a market for the drug. It will simply tap into Galderma's Oracea® market. If Mylan is permitted to market its generic copies of Oracea®, it will spend almost nothing on marketing. Instead, it will hitch a free ride on Galderma's marketing investment. *See Impax Labs., Inc. v. Aventis Pharms., Inc.*, 235 F. Supp. 2d 390, 396 (D. Del. 2002) (Farnan, J.) (finding that an injunction against a generic manufacturer would only cause "minimal hardship because doing so will leave [the generic] in the same position as it was before the injunction was granted . . .").

Moreover, Mylan will not bear any substantial costs in preparing for the manufacture of

the Generic Products. Mylan already markets and manufactures doxycycline tablets from components that can readily be used for the production of its Generic Products. REDACTED [redacted] Therefore, it is likely that Mylan has made minimal, if any, investment in anticipation of manufacturing the Generic Products.

Any harm Mylan would suffer through the issuance of an injunction will be negligible, consisting largely of the projected revenues from the sale of the generic drug, and cannot trump Galderma's irreparable losses. "Simply put, an alleged infringer's loss of market share and customer relationships, without more, does not rise to the level necessary to overcome the loss of exclusivity experienced by a patent owner due to infringing conduct." *Pfizer, Inc. v. Teva Pharms. USA, Inc.*, 429 F.3d 1364, 1382 (Fed. Cir. 2005). Mylan is a large company that sells over 200 generic drugs in the United States alone. *See* Ex. CC, 2008 Mylan Annual Report, at 11. In 2008, Mylan generated $1.85 billion in revenues from generic drug sales in North America. *See id.* at 3. At the end of 2008, Mylan had 120 pending ANDAs seeking approval to market additional generic drugs in the United States, 32 of which provide Mylan with the opportunity to obtain 180 days of exclusive generic marketing. *See id* at 11. Mylan's generic version of Oracea® is but one of a substantial number of products in Mylan's portfolio.

Moreover, as the first ANDA filer seeking to make a copy of Oracea®, Mylan is entitled to a 180-day period of exclusive marketing for its Generic Products. This exclusivity period does not start to run until Mylan first engages in the commercial marketing of its Generic Products. *See* 21 U.S.C. § 355(j)(5)(B)(iv) . In the meantime, no other generic manufacturer of Oracea® can enter the market. *See id.* Thus, any adverse impact of a preliminary injunction on Mylan is minimal because Mylan's potential market share remains intact until its 180-day exclusivity period expires. Because there are over six months until the scheduled trial in this action, if Mylan launches now, its 180-day exclusivity will run before trial, potentially enabling other generic manufacturers (such as Lupin and Impax) to enter the market with copies of Oracea® and causing further irreparable harm to Plaintiffs.

C. Mylan's Knowing Infringement Tips The Balance Of Hardships

Mylan, well aware of Galderma's patents, and with a full appreciation of the risks it is taking, seeks to introduce a directly competitive, infringing product. This factor tips the balance in favor of an injunction. *See Rubbermaid Commercial Prods., Inc. v. Contico Int'l, Inc.*, 836 F. Supp. 1247, 1258 (W.D. Va. 1993) (noting that a defendant's "knowing entrance into a risky venture lays much of the harm at its own doorstep"); *Ranbaxy Labs. Ltd. v. Abbott Labs.*, No. 04 C 8078, 05 C 1490, 2005 WL 3050608, at *30 (N.D. Ill. Nov. 10, 2005) (hardship associated with drug manufacturer's loss of market share outweighs potential hardship to generic manufacturers.)

IV. THE PUBLIC INTEREST WILL BE SERVED BY ISSUANCE OF A PRELIMINARY INJUNCTION

It is well-settled law that "public policy favors the protection of the rights secured by . . . valid patents." *Smith Int'l, Inc. v. Hughes Tools Co.*, 718 F.2d 1573, 1581 (Fed. Cir. 1983). In particular, the development of new pharmaceuticals depends largely upon the expectation of patent protection, given the extensive costs of bringing a new drug to market, and the substantial risks of failure along the way. Thus, "the public interest favors encouraging investment in drug development by protecting and enforcing . . . valid pharmaceutical patent[s]." *Ortho McNeil Pharm., Inc. v. Barr Labs., Inc.*, Civil Action No. 03-4678 (SRC), 2009 WL 2182665, at *11 (D.N.J. July 22, 2009); *see also Sanofi-Synthelabo*, 470 F.3d at 1383-84 ("We have long acknowledged the importance of the patent system in encouraging innovation."); *Hybritech*, 849 F.2d at 1458.

Congress encourages the public policy of protecting valid patents in the pharmaceutical industry. *See Pfizer*, 429 F.3d at 1382 ("[W]hile the statutory framework under which [defendant] filed its ANDA does seek to make low cost generic drugs available to the public, it does not do so by entirely eliminating the exclusionary rights conveyed by pharmaceutical patents. Nor does the statutory framework encourage or excuse infringement of valid pharmaceutical patents.").

Indeed, the public interest in protecting pharmaceutical patent rights (and the innovation that they encourage) supersedes the public interest in the availability of low-cost generic drugs. *See id.*; *Impax Labs.*, 235 F. Supp. 2d at 397 ("[T]here is a strong public interest in protecting valid patents by preventing the premature entry of generic drugs into the marketplace."). Mylan's ability to reap the bounty of Galderma's substantial labors in the development and marketing of Oracea® and thereby sell a lower priced generic product does not justify Mylan's infringement of Galderma's valid patents. *See Payless Shoesource, Inc. v. Reebok Int'l Ltd.*, 998 F.2d 985, 991 (Fed. Cir. 1993). Therefore, the Federal Circuit has noted that "[w]ere [lower price] to be a justification for patent infringement, most injunctions would be denied because copiers universally price their products lower than innovators." *Id.*

REDACTED For example, Galderma has recognized that rosacea is an under-diagnosed and often untreated disease. Consequently, Galderma runs educational programming to inform affected individuals about the disease as well as treatment options. REDACTED Additionally, Plaintiffs NYU and Research Foundation REDACTED are non-profit institutions that fund research and development that benefit the public.

CONCLUSION

For all of the foregoing reasons, Galderma submits that a temporary restraining order and a preliminary injunction against Mylan's present and continuing infringement are necessary in order to preserve the *status quo* until the Court has determined the merits of enjoining Mylan for the life of the Galderma patents.

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April 2, 2010

CERTIFICATE OF SERVICE

I hereby certify that on April 9, 2010, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to:

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David E. Moore, Esquire
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I further certify that I caused copies of the foregoing document to be served on April 9, 2010, upon the following in the manner indicated:

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